REMARKS

Claims 1, 3-6, 9, 10, 13-18, 20, 21, 24-28, 30-39, and 42-53 are pending and stand rejected. Claims 32 and 33 are withdrawn from consideration. Applicants respectfully request reconsideration of the present application in view of the following remarks.

Rejections Pursuant to 35 U.S.C. §102

Claims 1, 3-6, 9, 10, 13-18, 20, 21, 24-28, 30, 31, 34-39, 42-44, 46-50, 52, and 53 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent Publication No. 2003/078617 of Schwartz et al. ("Schwartz"). Applicants respectfully disagree with the Examiner's rejection.

Claim 1

Claim 1 recites a composite implant for repairing a tissue defect in a patient. The implant comprises a wedge-shaped porous tissue scaffold formed from a bioresorbable, synthetic polymeric material, and includes at least one pocket containing a viable tissue.

Schwartz fails to teach or even suggest a composite implant including at least one pocket containing a *viable tissue*. The Examiner argues that Schwartz "shows (Fig. 23) that there is a tissue material 22 placed in a pocket or hollow interior or lumen." However, Schwartz actually teaches a "mass of tissue regeneration material 22." The tissue regeneration material (22) "encompasses naturally occurring extracellular matrix (ECM) materials that provide a collagen scaffold for tissue repair and regeneration." *See* Schwartz at Par. 0083. The tissue regeneration material (22) formed from ECM materials is not a viable tissue as required by claim 1. Indeed, Schwartz explains that "the terms 'naturally occurring extracellular matrix' and 'naturally occurring ECM" are intended to refer to extracellular matrix material that has been cleaned, disinfected, sterilized, and optionally cross-linked." *Id.* Although the tissue regeneration material (22) is derived from natural tissue, there is no teaching or suggestion in Schwartz that the tissue regeneration material is "a viable tissue," as required by claim 1.

Furthermore, the addition of cells to the tissue regeneration material (22) using the techniques taught by Schwartz does not produce a viable tissue. The result is merely processed

ECM that is "seeded with living cells." Schwartz at Par. 0144. Although such a technique provides a convenient delivery vehicle for the cells, the delivery vehicle is not a viable tissue with or without the addition of cultured cells. The use of processed ECM seeded with cultured cells involves isolation and amplification of cells in culture. However, in Applicant's invention, a scaffold is associated with viable tissue to allow for the direct delivery of viable cells to the site of injury or defect without the cost associated with the isolation and amplification of cells in culture. In addition, the time required for carrying out a repair is shortened, since there is no need to procure healthy tissue and then isolate and amplify cells for seeding the scaffold prior to implantation surgery. *See* Published Application at Par. 0004-0005.

Claim 13

Claim 13 recites a composite implant for tissue repair comprising a wedged shaped porous scaffold having at least one pocket therein. Viable tissue, such as minced tissue, sliced tissue, or slivered tissue is disposed within the scaffolds' pocket.

As discussed above with respect to claim 1, Schwartz fails to teach or even suggest a composite implant including *viable tissue* disposed within a pocket in the scaffold. The tissue regeneration material (22) taught by Schwartz is created by processing "naturally-occurring extracellular matrix" into "a scaffold for tissue repair and regeneration." *See* Schwartz at Par. 0083. The Examiner argues that "Schwartz et al. disclose that tissue is obtained and comminuted (i.e. mince, slice or sliver) to smaller fragments and then loaded between of within the pocket of the tissue scaffold." However, Schwartz does not teach or even suggest the use of viable tissue comprising at least one of minced, sliced, and/or slivered tissue fragments, as required by claim 13. The processing steps cited by the Examiner are used to process ECM to create a scaffold. *See* Schwartz at Par. 0123. As discussed above, ECM is not viable tissue, and although the process of creating a scaffold from ECM includes a comminuting step, the result is processed ECM, not viable tissue.

Claims 24 and 34

Claims 24 and 34 recite methods for repairing defective tissue. The claimed methods comprise obtaining a viable tissue and loading the viable tissue, or fragments thereof, into at least one pocket formed by an opening in the sidewall of a tissue scaffold.

The Schwartz reference does not teach or suggest the claimed method for tissue repair. The Examiner argues that Schwartz "shows (Fig. 23) that there is a tissue material 22 placed in a pocket or hollow interior or lumen." However, as discussed above with respect to claims 1 and 12, Schwartz fails to disclose the use of *viable tissue* in a method for tissue repair. The "tissue material 22" disclosed by Schwartz is actually "cleaned, disinfected, sterilized, and optionally cross-linked" extracellular matrix material. *See* Schwartz at Par. 0083. Schwartz does not teach or suggest obtaining a viable tissue or loading viable tissue into a pocket of the tissue scaffold. The tissue regeneration material (22) disclosed by Schwartz is produced by processing extracellular matrix materials. *Id.* The processed ECM is not viable tissue. Although Schwartz discloses that the processed ECM may be "seeded with living cells," the resulting tissue regeneration material does not contain viable tissue and is not, itself, a viable tissue. *See* Schwartz at Par. 0144. As discussed above, the tissue regeneration material disclosed by Schwartz is merely a convenient delivery vehicle for the cells seeded thereon.

Accordingly, independent claims 1, 13, 24, and 34 distinguish over Schwartz and represent allowable subject matter. Claims 3-6, 9, 10, 14-18, 20, 21, 25-28, 30-33, 35-39, and 42-53 are allowable at least because they depend from an allowable base claim.

Rejections Pursuant to 35 U.S.C. §103

Claims 45 and 51 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Schwartz. Applicants respectfully disagree with the Examiner's rejection.

At the outset, Applicants note that claims 45 and 51 incorporate the recitations of their respective base claims and thus distinguish over Schwartz for at least the reasons discussed above with respect to the base claims. In particular, independent claims 13 and 34, from which claims 45 and 51 depend, require that the minced, sliced or slivered tissue fragments are viable

tissue fragments. Schwartz does not teach or even suggest forming fragments of viable tissue. Schwartz discloses that ECM materials are comminuted or shredded in the process of creating an ECM scaffold. *See* Schwartz at Par. 0122-0123. However, there is no teaching or suggestion in Schwartz that would lead one of ordinary skill in the art to utilize fragments of viable tissue, let alone fragments of viable tissue of the claimed particle size.

The Examiner admits that "Schwartz fails to explicitly disclose the tissue fragments are of a particular size having the dimension of 0.5 mm^3 to 3 mm^3." The Examiner argues that Schwartz discloses "that the particle size can be any dimension and is not to be limited to particular dimensions, paragraph 122." The Examiner then argues that "it would have been obvious to one of ordinary still in the art to utilize a particle dimension as claimed since such a modification only involves routine skill in the art and varying the size would not affect the function of the cells." The Examiner's arguments are incorrect. As discussed in detail above, Schwartz does not teach or suggest the use of viable tissue fragments. Schwartz only discloses that the "particular size of ECM fiber material" is not limited to particular dimensions. *See* Schwartz at Par. 0122. In addition, the processing steps cited by the Examiner are actually used to process ECM to create a scaffold, which is then seeded with cultured cells. Cultured cells are very different from fragments of viable tissue, and cells obtained through cell culture, even when seeded onto the tissue regeneration material disclosed by Schwartz, are not equivalent to viable tissue fragments obtained from body tissue. Viable tissue fragments include tissue components that are simply not present in cell culture or when cultured cells are seeded onto a delivery device. These tissue components affect the production, handling, and effectiveness of the tissue fragments themselves as well as the resulting implant.

Finally, tissue fragment size is critical to the success of an implant that uses tissue fragments. For example, the enclosed paper discloses that both the respiratory and functional activity of tissue fragments is dependent on the size of the fragments. Solov'ev et al., *Functional Activity of Hepatocytes in Liver Fragments In Vitro as a Function if Fragment Size and Duration of Culturing*, Bulletin of Experimental Biology and Medicine, Oct. 1997, 977-9 (showing that succinate stimulation coefficient, rate of oxygen uptake, urea synthesis, NA demethylation, and ethanol oxidation are dependent on tissue fragment size). The research conducted by Solov'ev, clearly shows that varying the size of the tissue fragments does affect the function of cells.

Consequently, the Examiner's statement that "it would have been obvious to one of ordinary still in the art to utilize a particle dimension as claimed since such a modification only involves routine skill in the art and varying the size would not affect the function of the cells" is incorrect and directly contradicted by the well-established art at the time the invention was made.

Accordingly, claims 45 and 51 distinguish over Schwartz and represent allowable subject matter.

Conclusion

In conclusion, Applicants submit that all claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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